## Department of Consumer Affairs Title 16. California State Board of Optometry

## PROPOSED REGULATORY LANGUAGE

Radiofrequency Technology

Legend:

Originally Proposed text additions are indicated with an <u>underline</u>. Modified Proposed text additions are indicated with a <u>double underline</u>. Modified Proposed text deletions are indicated with a <del>strikeout</del>.

Add section 1572 in Article 11 of Division 15 of Title 16 of the California Code of Regulations to read as follows:

## § 1572. Radiofrequency Technology; Authorization and Requirements

(a)The use of noninvasive medical devices or radiofrequency technology, as defined in this section, for treatment of dry eye disease or syndrome is authorized for use by Board licensed, TPA certified optometrists meeting the requirements of this section.

(b) The following requirements must be met prior to using radiofrequency technology or devices:

 <u>A TPA certified optometrist who uses radiofrequency technology must have proof</u> as specified in this section of the optometrist's completion of appropriate clinical training available on-site for Board inspection and upon request. Proof of appropriate clinical training can be satisfied by the following:

(A) a document signed and dated by an authorized representative of the manufacturer of the applicable medical device showing the optometrist received a training provided by the manufacturer on the use of the applicable radiofrequency technology or medical device of at least one (1) credit hour,

(B) a certificate of completion or other document signed and dated by an authorized representative of a continuing education provider specifying that the optometrist completed a Board-approved continuing education course worth at least one (1) credit hour in radiofrequency technology, or,

(C) original transcripts certified by the appropriate official responsible for the records such as the registrar, showing the optometrist received radiofrequency training at an optometric college as part of the curriculum required to obtain the optometric degree.

2) <u>An optometrist shall only use noninvasive radiofrequency technology or devices</u> on patients and only for the optometric purpose of treating dry eye disease or syndrome as documented in the patient's medical record. An optometrist shall not provide radiofrequency treatment to a patient solely for aesthetic benefit or after the optometric purpose for the treatment has been achieved.

- 3) <u>An optometrist shall not delegate the use of the radiofrequency technology or device to any other person, including opticians.</u>
- 4) <u>All equipment or medical devices should be maintained, tested and inspected according to the manufacturers' specifications. The optometrist must retain a copy of the manufacturer's specifications for the radiofrequency technology or medical device on-site for Board inspection and upon request.</u>

(c) For the purposes of this section, the following definitions shall apply:

1) "Noninvasive medical devices or radiofrequency technology" means the use of noninvasive medical devices, that do not rely on laser technology, that deliver an electromagnetic current or wave to the skin of a patient for the purpose of heating the tissue treating dry eye disease or syndrome. The electromagnetic current or wave frequency used for treating dry eye disease or syndrome shall be between 1 MHz and 6 MHz and the medical device which delivers the electromagnetic current or wave frequency shall contain a built-in temperature sensor which displays in real-time the temperature on the surface of the skin or contain temperature presets which shut down the device if the preset temperature is exceeded. The temperature applied to the surface of the skin shall not exceed 43 degrees Celsius or 109.4 degrees Fahrenheit.

2) "Credit hour" includes the definition prescribed by Section 1536.

3) "Board-approved continuing education course" shall include a course meeting the requirements of Section 1536.

Note: Authority cited: Sections 3025 and 3041, Business and Professions Code. Reference: Section 3041, Business and Professions Code.